Office of the Secretary Curtis State Office Bldg. 1000 SW Jackson Suite 540 Topeka, Kansas 66612



Phone: 785-296-0461 Fax: 785-368-6368

Robert Moser, MD, Secretary

Department of Health & Environment

Sam Brownback, Governor

January 19, 2012

Barbara Dominguez
Office of the Secretary of State
120 SW 10th St.
Topeka KS 66612

RE:

Filing Notice of Hearing for Proposed Administrative Regulations

KAR 28-56-1, 28-56-2, 28-56-3, 28-56-4, 28-56-5, 28-56-6, 28-56-7, 28-56-8, 28-56-9, 28-56-10

Dear Ms. Dominguez:

Attached are two copies of the above-referenced Kansas Department of Health and Environment proposed new permanent Article 56 regulations. Two copies of the economic impact statement are also included.

Also attached are two copies of the notice of public hearing for these regulations. The public hearing is scheduled for April 16, 2012, at 10:00 a.m. in Room 530, Curtis State Office Bldg., Topeka. Please cause the notice of public hearing to be published in the *Kansas Register*.

If you have any questions or need any further information regarding filing of the notice of hearing for these regulations, please contact Susan Vogel at 296-1291 or svogel@kdheks.gov.

Sincerely,

Robert Moser, MD

Secretary of Health and Environment

Attachments

pc w/notice of hearing only

Sen. Vicki Schmidt, Chair, Joint Committee on Rules and Regulations

Rep. Carl Holmes, Vice-Chair, Joint Committee on Rules and Regulations

Rep. Janice Pauls, Ranking Minority Member, Joint Committee on Rules and Regulations

Raney Gilliland, Legislative Research

State of Kansas Department of Health and Environment

Notice of Hearing on Proposed Administrative Regulations

The Kansas Department of Health and Environment, Division of Health, Bureau of Public Health Informatics, will conduct a public hearing at 10 a.m. Monday, April 16, in Room 530, Curtis State Office Building, 1000 S.W. Jackson, Topeka, to consider the adoption of new regulations K.A.R. 28-56-1, 28-56-2, 28-56-3, 28-56-4, 28-56-5, 28-56-6, 28-56-7, 28-26-8, 28-56-9 and 28-56-10, pertaining to the reporting of abortions.

A summary of the proposed regulations and the estimated economic impact follows: Summary of Regulations:

- 28-56-1. Definitions. Defines terms used in these regulations.
- 28-56-2. General requirements for abortion reports. Specifies the information to be reported on every abortion report submitted to the department; requires reports within 15 days of abortion; requires confidential code number; requires provider to have copy of reporting requirements; requires electronic reporting for certain reports.
- 28-56-3. Reporting requirements for abortions performed at clinical estimate of gestation of at least 22 weeks. Establishes additional reporting requirements for abortions performed at 22 weeks or greater gestation; requires specific responses to clinical issues; requires medical codes be submitted with the information.
- 28-56-4. Reporting requirements for partial birth abortions. Establishes additional reporting requirements for partial birth abortions; requires specific responses to clinical issues; requires medical codes be submitted with the information.
- **28-56-5.** Requirements for reporting failed abortions. Requires filing of a failed abortion report if abortion attempt results in a live birth; requires submission of live birth certificate as well.

- 28-56-6. Reporting requirements for abortions performed on minors in the case of a medical emergency. Requires physicians to report additional information about abortions performed on minors in case of medical emergencies.
- 28-56-7. Physician's report of number of certifications received. Requires physicians to file a monthly report on number of informed consent certifications received prior to performing an abortion; specifies information to be provided.
- **28-56-8.** Late term affidavits. Requires physicians performing and referring late-term abortions to sign separate affidavits attesting the physicians are not legally or financially affiliated.
- 28-56-9. Correction in an abortion report. Establishes procedures and timeframe for correcting abortion reports and reports on the number of informed consent certifications received by physicians.
- **28-56-10.** Medical information retained on each abortion performed. Establishes the medical information that must be retained on each abortion performed by a provider.

Economic Impact:

Cost to individuals: These proposed regulations are consistent with current abortion records reporting requirements and should not impose any additional or unusual cost on regulated providers or clients. There are no fees assessed to the regulated community. Some additional time may be spent by providers to comply with new record-keeping and reporting requirements. However, although difficult to estimate, that time is likely to be modest.

Cost to the agency: Revisions to forms and abortion reporting software and staff time for training providers will be required. Costs are estimated to be \$34,000 with the bulk of the money expended for the vendor maintaining the vital statistics information system to modify the abortion

reporting system. It is presumed these costs will be absorbed in the current budget. Processing reports submitted to the agency will be accomplished by existing staff.

Costs to other governmental agencies or units: There are no known costs to other agencies.

The time period between publication of this notice and the scheduled hearing serves as the required public comment period of at least 60 days for the purpose of receiving written public comments on the proposed new regulations. At any time during the public comment period interested parties may submit written comments to Elizabeth W. Saadi, Ph.D., Deputy Director, BEPHI, and State Registrar, KDHE, 1000 S.W. Jackson, Suite 110, Topeka 66612, by e-mail to Isaadi@kdheks.gov or by fax to (785) 368-7118. During the hearing, all interested parties will be given a reasonable opportunity to present their views orally on the proposed new regulations as well as an opportunity to submit their written comments. In order to give each individual an opportunity to present their views, it may be necessary for the hearing officer to request that each presenter limit any oral presentation to an appropriate time frame.

Complete copies of the proposed regulations and the corresponding economic impact statement may be obtained on the Bureau of Public Health Informatics website at www.kdheks.gov/ches or by contacting Elizabeth W. Saadi, Ph.D., Deputy Director, BEPHI, and State Registrar, at the address above, phone (785) 296-8627 or fax (785) 368-7118. Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulations and economic impact statements in an accessible format. Requests for accommodation should be made at least five working days in advance of the hearing by contacting Dr. Saadi.

Robert Moser, M.D.

Secretary of Health and Environment

K.A.R. 28-56-1. Definitions. Each of the following terms shall have the meaning assigned in this regulation:

- (a) "Abortion" has the meaning specified in K.S.A. 65-6701, and amendments thereto.
- (b) "Abortion provider" means a physician that performs an abortion, a clinic comprised of legally or financially affiliated physicians, a hospital, or any other medical care facility where an abortion is performed.
- (c) "Abortion report" means the information required to be submitted by an abortion provider to the department either electronically or on a paper form provided by the department.
- (d) "Clinical estimate of gestation" means the number of completed weeks of gestation of an unborn child as determined through a sonogram.
- (e) "Confidential code number" means a random five-digit identification number, along with subcategory letters, assigned by the department to an abortion provider for the purpose of submitting an abortion report to the department.
- (f) "Correction" means the act of providing information to the department to correct errors or provide missing information to an abortion report.
 - (g) "Department" has the meaning specified in K.S.A. 65-6701, and amendments thereto.
- (h) "Electronic abortion reporting system" means the department's vital events reporting system through which abortion reports are submitted electronically to the department.
- (i) "Failed abortion" means an abortion procedure that was initiated but not completed and resulted in a live birth.
- (j) "Failed abortion report" means the information on a failed abortion required to be submitted by the abortion provider to the department on a paper form provided by the

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department.

- (k) "Hospital" has the meaning specified in K.S.A. 65-425, and amendments thereto.
- (1) "ICD-9-CM" means volumes one and two, office edition, of the 2011 clinical modification of the "international classification of diseases," ninth revision, sixth edition, published by practice management information corporation, which is used to code and classify morbidity data from inpatient and outpatient records, physician offices, and most surveys from the national center for health statistics. This document, including the appendices, is hereby adopted by reference.
 - (m) "Late term" means the clinical estimate of gestation of at least 22 completed weeks.
- (n) "Late term affidavit" means a department-provided form for each abortion that occurs at a clinical estimate of gestation of at least 22 weeks. The referring physician and the physician performing the abortion shall each submit a separate form, which shall be completed, signed, and notarized and shall meet the requirements of K.A.R. 28-56-6.
 - (o) "Live birth" has the meaning specified in K.S.A. 65-2401, and amendments thereto.
- (p) "Medical basis" means the specific medical signs, symptoms, history, or other information provided by the patient or the results of clinical examinations, procedures, or laboratory tests used to make a medical diagnosis.
- (q) "Medical care facility" has the meaning specified in K.S.A. 65-425, and amendments thereto.
- (r) "Medical diagnosis" means a specific medical condition or disease as determined by a physician.

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- (s) "Medical emergency" has the meaning specified in L. 2011, ch. 82, sec. 1, and amendments thereto.
- (t) "Partial birth abortion" has the meaning specified in K.S.A. 65-6721, and amendments thereto.
 - (u) "Physician" has the meaning specified in K.S.A. 65-6701, and amendments thereto.
- (v) "Physician's report on number of certifications received" means a monthly report that shall be submitted to the department on a form provided by the department specifying the number of voluntary and informed consent forms certified by each patient and received by the physician before the patient is to receive an abortion.
- (w) "Referring physician" means a physician who refers a patient to an abortion provider and who is required to provide a late term affidavit.
- (x) "Requirements related to reporting abortions" means the department's handbook containing instructions describing how abortions shall be reported to the department, either on a paper form or electronically, and copies of applicable state statutes and regulations.
- (y) "User agreement" means the required document that entitles each abortion provider or the designee to access the department's electronic abortion reporting system.
- (z) "Unborn child" means a living individual organism of the species Homo sapiens, in utero, at any stage of gestation from fertilization to birth.
 - (aa) "Viable" has the meaning specified in K.S.A. 65-6701, and amendments thereto.
- (bb) "Voluntary and informed consent form" means the form provided by the department that is signed by the patient authorizing an abortion provider to perform an abortion.

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K.A.R. 28-56-2. General requirements for abortion reports. (a) Each abortion provider shall complete and file an abortion report within 15 days of the initiation of each abortion.

- (b) Each abortion provider, before performing an abortion and before using the electronic abortion reporting system, shall obtain the following:
 - (1) A confidential code number from the department; and
 - (2) a copy of the requirements related to reporting abortions.
- (c) Each abortion provider performing less than five abortions annually may use the paper form abortion report.
- (d) Each abortion provider performing five or more abortions annually shall use the electronic abortion reporting system to file each abortion report and shall meet the following requirements:
 - (1) Submit an executed user agreement; and
- (2) ensure that each individual authorized by the abortion provider to enter abortion data into the electronic abortion reporting system has a separate user account to access the electronic abortion reporting system.
- (e) Each abortion provider shall file an abortion report for each abortion performed. Each abortion report shall include the confidential code numbers of the abortion provider for each abortion performed. The abortion report from a hospital, clinic, or any other medical care facility shall be in addition to the abortion report from the physician who performed the abortion.
- (f) Each abortion provider shall file an abortion report containing the following information:

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- (1) The abortion provider's confidential code number;
- (2) the patient's unique identification number as maintained in the abortion provider's medical record. The patient's name and street address shall not be submitted;
 - (3) the patient's age in years on the patient's last birthday;
 - (4) the patient's marital status at the time of the abortion;
 - (5) the month, day, and year the abortion was performed;
- (6) the state or United States territory of residence of the patient or, if the patient is not a resident of the United States, the patient's country of residence;
- (7) the patient's county of residence if the patient is a resident of a state or territory of the United States or, if the patient is a resident of Canada, the province;
 - (8) the patient's city or town of residence;
- (9) specification of whether the patient resided within the city limits of the city or town of residence;
 - (10) the hispanic origin of the patient, if applicable;
 - (11) the patient's ancestry;
 - (12) the patient's race;
 - (13) the highest level of education completed by the patient;
- (14) the date when the patient's last normal menses began, including the month, day, and year as reported by the patient;
 - (15) clinical estimate of gestation;
 - (16) number of previous pregnancies, in the following categories:

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	(B) sharp curettage;
	(A) Suction curettage;
includ	ling any of the following procedures that apply:
	(18) if applicable, all secondary abortion procedures used in terminating the pregnancy,
	(K) other procedure, which shall be specified;
	(J) partial birth abortion; or
	(I) digoxin induction;
	(H) hysterectomy;
	(G) hysterotomy;
	(F) prostaglandins delivered by intrauterine instillation or other methods;
	(E) administration of methotrexate;
	(D) administration of mifeprestone;
	(C) dilation and evacuation;
	(B) sharp curettage;
	(A) Suction curettage;
the fo	llowing abortion procedures:
	(17) the primary abortion procedure used in terminating the pregnancy, including one of
	(D) previous spontaneous terminations, including miscarriages, or stillbirths;
	(C) previous induced abortions; and
	(B) children born live and now dead;
	(A) Children born live and now living;

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(C) dilation and evacuation;			
(D) administration of mifeprestone;			
(E) administration of methotrexate;			
(F) prostaglandins delivered by intrauterine instillation or other methods;			
(G) hysterotomy;			
(H) hysterectomy;			
(I) digoxin induction;			
(J) partial birth abortion; or			
(K) other procedure, which shall be specified;			
(19) specification of the medical factors and methods used to determine the clinical			
estimate of gestation; and			
(20) specification of whether there was a report of physical, mental, or emotional abuse			
or neglect filed pursuant to K.S.A. 38-2223, and amendments thereto. (Authorized by K.S.A. 65-			
445, as amended by L. 2011, ch. 41, sec. 4 and L. 2011, ch. 44, sec. 2, and K.S.A. 65-6703, as			
amended by L. 2011, ch. 44, sec. 4; implementing K.S.A. 65-6703, as amended by L. 2011, ch.			
44. sec. 4: effective P-			

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K.A.R. 28-56-3. Reporting requirements for abortions performed at clinical estimate of gestation of at least 22 weeks. When performing an abortion at clinical estimate of gestation of 22 or more weeks, in addition to the requirements specified in K.A.R. 28-56-2, each abortion report shall contain the following information:

- (a) Specification of whether the unborn child was viable;
- (b) a detailed, case-specific description that includes the medical diagnosis and medical basis of the patient and unborn child if the unborn child was viable;
- (c) specification of whether continuation of the pregnancy would cause a substantial and irreversible impairment of a major bodily function or the death of the patient;
- (d) a detailed, case-specific description that includes the medical diagnosis and medical basis for the determination that the abortion was necessary to prevent the patient's death or irreversible impairment of a major bodily function; and
- (e) a medical determination that includes all applicable medical diagnosis codes from the ICD-9-CM. (Authorized by K.S.A. 65-6703, as amended by L. 2011, ch. 44, sec. 4 and L. 2011, ch. 41, sec. 3; implementing K.S.A. 65-6703, as amended by L. 2011, ch. 44, sec. 4; effective P-

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K.A.R. 28-56-4. Reporting requirements for partial birth abortions. For each procedure performed involving a partial birth abortion, in addition to the requirements specified in K.A.R. 28-56-2 and 28-56-3, each abortion report for a partial birth abortion shall contain the following information:

- (a) Specification of whether the unborn child was viable;
- (b) a detailed, case-specific description that includes the medical diagnosis, medical basis, and description of the medical conditions of the patient and unborn child if the unborn child was viable;
- (c) specification of whether continuation of the pregnancy would cause a substantial and irreversible impairment of a major bodily function or the death of the patient;
- (d) a detailed, case-specific medical diagnosis and medical basis for the determination that the abortion was necessary to prevent the patient's death or irreversible impairment of a major bodily function; and

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K.A.R. 28-56-5. Requirements for reporting failed abortions. If an abortion attempt fails and results in a live birth, each abortion provider shall complete and file the following information:

- (a) A certificate of live birth pursuant to K.S.A. 65-2409a, and amendments thereto; and
- (b) a failed abortion report meeting the following requirements:
- (1) Meeting the requirements specified in K.A.R. 28-56-2; and
- (2) specifying the medical basis and medical diagnosis for the reason the abortion was not completed. (Authorized by and implementing K.S.A. 65-445, as amended by L. 2011, ch. 41, sec. 4 and L. 2011, ch. 44, sec. 2; effective P-______.)

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- K.A.R. 28-56-6. Reporting requirements for abortions performed on minors in the case of a medical emergency. (a) Each abortion provider shall file an abortion report as specified in K.A.R. 28-56-2 and, if applicable, K.A.R. 28-56-3.
- (b) Each abortion report for an abortion performed on a minor during a medical emergency shall contain the following information:
 - (1) If applicable, the information specified in K.A.R. 28-56-4 and K.A.R. 28-56-5;
 - (2) the medical basis for determining that a medical emergency exists;
 - (3) the medical methods used in determining the medical emergency;
- (4) the patient identification number obtained from the patient's medical records where the abortion was performed; and

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K.A.R. 28-56-7. Physician's report on number of certifications received. (a) Each physician performing an abortion shall submit to the department the number of patient-completed voluntary and informed consent forms as specified in K.S.A. 65-6709, and amendments thereto. The report shall be submitted within five business days after the end of each month.

- (b) Each physician's report on number of certifications received shall be submitted by

 United States mail or facsimile transmission. The report shall contain the following information:
 - (1) The physician's confidential code number;
 - (2) the date the report was submitted; and
- (3) the number of voluntary and informed consent forms as specified in K.S.A. 65-6709, and amendments thereto, received during the previous calendar month, including any voluntary and informed consent form that was not followed by an abortion.
- (c) Each correction to the physician's report on the number of certifications received shall be made within 15 business days of discovery of the error or omission. (Authorized by K.S.A. 65-445, as amended by L. 2011, ch. 41, sec. 4 and L. 2011, ch. 44, sec. 2, and K.S.A. 2010 Supp. 65-6709, as amended by L. 2011, ch. 44, sec. 6; implementing K.S.A. 2010 Supp. 65-6709, as amended by L. 2011, ch. 44, sec. 6; effective P-_______.)

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K.A.R. 28-56-8. Late term affidavits. (a) The referring physician and the physician performing an abortion shall each submit a late term affidavit to the department within 15 business days of the completion of the abortion procedure.

- (b) The late term affidavit completed by the referring physician shall contain the following information:
 - (1) Name of the referring physician;
- (2) the patient's identification number obtained from the patient's medical records where the abortion was performed;
- (3) a statement that the referring physician and the physician performing the abortion have no legal or financial affiliation with each other as specified in K.S.A. 65-6703, and amendments thereto; and
 - (4) the date the late term affidavit was signed and notarized.

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K.A.R. 28-56-9. Correction in an abortion report. (a) In case of an error or missing information in an abortion report, each abortion provider shall report in writing to the department within 15 business days of discovery the specific information that needs to be corrected or provided.

- (b) Each abortion provider shall review all relevant medical records after being advised by the department of an error or missing information on the abortion report and shall provide any correction or updated information on the abortion report within 15 business days of discovery of the error or omission.
- (c) An abortion provider shall not make corrections or additions to an abortion report within the electronic abortion reporting system or create a new record to replace the incorrect or incomplete abortion report. (Authorized by and implementing K.S.A. 65-445, as amended by L. 2011, ch. 41, sec. 4 and L. 2011, ch. 44, sec. 2; effective P-_______.)

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K.A.R. 28-56-10. Medical information retained on each abortion performed. (a) Each abortion provider shall retain the following information in each patient's medical record for at least 10 years:

- (1) A copy of the abortion report and any subsequent corrections;
- (2) a copy of the voluntary and informed consent form;
- (3) a copy of the late term affidavit of the physician who performed the abortion;
- (4) a copy of a court-ordered bypass of parental consent as specified in K.S.A. 65-6705, and amendments thereto, or consent of the parent or legal guardian if the minor is not emancipated;
 - (5) the physical or mental medical history of the patient;
 - (6) all sonogram results;
- (7) a copy of the medical basis and reasons related to partial birth abortion, late term abortion, or emergency abortion procedure on a minor;
- (8) a copy of the patient-specific counseling information provided in addition to state-required material;
 - (9) a copy of the postabortion instructions;
 - (10) a record and description of any complications;
 - (11) the type and amount of anesthesia used;
- (12) any report of physical, mental, or emotional abuse or neglect of a minor pursuant to K.S.A. 38-2223, and amendments thereto;

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- (13) a list of all medical tests performed and the results of each test;
- (14) a record of any return visit by patient, if indicated by the physician;
- (15) emergency contact information for the patient;
- (16) a copy of the medical referral from the referring physician; and
- (17) if known, the name, address, and telephone number of the father of the unborn child if the patient is less than 16 years old.
- (b) Each referring physician shall retain a copy of that physician's late term affidavits for at least 10 years. (Authorized by K.S.A. 65-445, as amended by L. 2011, ch. 41, sec. 4 and L. 2011, ch. 44, sec. 2, K.S.A. 65-6703, as amended by L. 2011, ch. 44, sec. 4, and L. 2011, ch. 41, sec. 3; implementing K.S.A. 65-445, as amended by L. 2011, ch. 41, sec. 4 and L. 2011, ch. 44, sec. 2, and K.S.A. 65-6703, as amended by L. 2011, ch. 44, sec. 4; effective P-

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Kansas Department of Health and Environment Economic Impact Statement

Pursuant to the requirements of KSA 2010 Supp. 77-416, the Kansas Department of Health and Environment submits the following economic impact statement.

1. Regulation(s):

K.A.R. 28-56-1

K.A.R. 28-56-2

K.A.R. 28-56-3

K.A.R. 28-56-4

K.A.R. 28-56-5

K.A.R. 28-56-6

K.A.R. 28-56-7

K.A.R. 28-56-8

K.A.R. 28-56-9

K.A.R. 28-56-10

2. Brief description of each regulation(s) and what is intended to be accomplished by adoption.

K.A.R. 28-56-1

Defines 28 terms used in the regulations.

K.A.R. 28-56-2

Specifies the information to be reported on every abortion report submitted to the department; requires reports within 15 days of abortion; requires confidential code number; requires provider to have copy of reporting requirements; requires electronic reporting for certain reports.

K.A.R. 28-56-3

Establishes additional reporting requirements for abortions performed at 22 weeks or greater gestation; requires specific responses to clinical issues; requires medical codes be submitted with the information.

K.A.R. 28-56-4

Establishes additional reporting requirements for partial birth abortions; requires specific responses to clinical issues; requires medical codes be submitted with the information.

K.A.R. 28-56-5

Requires filing of a failed abortion report if abortion attempt results in a live birth; requires submission of live birth certificate as well.

K.A.R. 28-56-6

Requires physicians to report additional information about abortions performed on minors in case of medical emergencies.

K.A.R. 28-56-7

Requires physicians to file a monthly report on number of informed consent certifications received prior to performing an abortion; specifies information to be provided.

K.A.R. 28-56-8

Requires physicians performing and referring late-term abortions to sign separate affidavits attesting the physicians are not legally or financially affiliated.

K.A.R. 28-56-9

Establishes procedures and timeframe for correcting abortion reports and reports on the number of informed consent certifications received by physicians.

K.A.R. 28-56-10

Establishes the medical information that must be retained on every abortion performed by every provider.

3. Is this regulation(s) mandated by federal law as a requirement for participating in or implementing a federally subsidized or assisted program?

Yes	Nox
If yes, please explain.	
Do the proposed regu	lations exceed the requirements of applicable federal law?
Yes	Nox

5. Description of Costs:

4.

a. Cost to the agency:

If yes, please explain.

Revisions to forms and abortion reporting software and staff time for training providers will be required. Costs are estimated to be \$34,000 with the bulk of the money expended for the vendor maintaining the vital statistics information system to modify the abortion reporting system. It is presumed the costs will be absorbed in the current budget.

b. Cost to persons who will bear the costs and those who will be affected, (i.e., private citizens and consumers of the products or services) and are subject to the proposed rules and regulations or the enforcement:

There are no fees assessed to the regulated community. Some additional time may be spent by providers to comply with new record-keeping and reporting requirements. However, that time is likely to be modest and difficult to estimate.

c. Costs to other governmental agencies or units:

There are no known costs to other agencies.

6. Description of any less costly or less intrusive methods that were considered by the agency for the purpose of the rules and regulations and why such methods were rejected in favor of the proposed rules and regulations.

No less costly or less intrusive methods were identified. Kansas law mandated KDHE promulgate the regulations. No alternatives were identified in state law.

7. Verification of economic impact statement with League of Kansas Municipalities, Kansas Association of Counties and the Kansas Association of School Boards.

Yes	No x	
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